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EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/035,042	KRYLOV ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17 and 19-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed on April 26, 2004 is acknowledged and has been entered. Claims 1,17 and 19 have amended. Claims 18 have been cancelled. Claims 1-17 and 19-23 are pending. All of the amendments and arguments have been thoroughly reviewed and considered but are deemed moot in view of the new grounds of rejections. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Previous Rejections

3. The prior art rejection under 35 USC 102(b) directed to claims 1-4, 7-14, 17-19 and 21 as being anticipated by Wang et al is withdrawn in view of Applicant's amendment of the claims. The prior art rejection rejections under 35 USC 102(b) directed to claims 17, 20 and 21 as being anticipated by Guschin et al. is maintained. The prior art rejection under rejections under 35 USC 103(a) directed to claims 5, and 6 as being obvious over Drobyshev et al is withdrawn in view of Applicant's amendment of the claims. The prior art rejection under rejections under 35 USC 103(a) directed to claims 15, 16, 22 and 23 as being obvious over Wang et al in view of Ahern is withdrawn in view of Applicant's amendment of the claims. The prior art rejection under rejections under 35 USC 103(a) directed to claims 5, and 6 as being obvious over Drobyshev et al is withdrawn in view of Applicant's amendment of the claims.

New Ground(s) of Rejections

THE NEW GROUND OF REJECTIONS ARE NECESSITATED BY APPLICANT'S AMENDMENT OF THE CLAIMS:

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-14 and 17, 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-14 is confusing and lacks proper antecedent basis in claim 1 at step (b) for "contacting the nucleic acid and the protein under conditions which allow the nucleic acid and protein to interact" because no prior step recites wherein "a nucleic acid and protein" has been provided for any interaction. The prior steps only recites that a nucleic acid *or* protein has been immobilized. Likewise, the claims 1-14 are *non sequitur* at step (b) for the "contacting" in claim 1 to the immobilization of a nucleic acid or protein in step (a) because their relationship is unclear. Specifically, the contacting step does not correlate to the step of "immobilizing a nucleic acid or protein within a solid support" because there is no indication from the steps that an interaction between a nucleic acid and protein has occurred. Clarification is required.

(b) Claims 1-14, 17, 19-21 are confusing at step (c) for "measuring the strength of the nucleic acid protein interaction" because it cannot be determined from the claims as written, especially steps a-b of claim 1 whether or not an interaction between a nucleic acid and protein has actually occurred. Additionally, the specification does not provide a

limiting definition for the term "strength" as it relates to interaction. Thus, it unclear as to how or what conditions are necessary to determine "strength" of interaction between a nucleic acid and protein or nucleic acid and nucleic acid or protein and protein. Clarification is required.

Claim Rejections - 35 USC § 102(b)

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-5, 7-9, 12-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Guschin et al (Analytical Biochemistry, vol. 250, pages 203-211, 1997). Regarding claims 1-3, Guschin et al teach a method for characterizing a nucleic acid and protein interaction comprising: (a) immobilizing a nucleic acid or protein within a solid support; (b) contacting the nucleic acid or protein with the immobilized nucleic acid or protein under conditions which allow the nucleic acid and protein to interact; and (c) measuring the strength of the nucleic acid and protein interaction with the nucleic acid or protein immobilized solid support. Guschin et al additionally teach wherein the method further comprises repeating the steps (a)-(c) one or more times and wherein the nucleic acid, protein or both used in repeated steps (a) through (c) are different from the respective nucleic acid, protein or both used in the first interaction (pages 204-207, entire section "Materials and Methods"; Figure 3-6).

Regarding claim 4, Guschin et al teach the method of claim 1, wherein the nucleic acid is selected from single stranded RNA or DNA or double-stranded DNA (page 204, col. 1, last paragraph bridging column 2, lines 1-2 and page 207, line 14).

Regarding claim 5, Guschin et al teach the method of claim 1, wherein the solid support is a gel pad (page 203, col. 2, last paragraph bridging page 204, col. 1, lines 1-3).

Regarding claim 7, Guschin et al teach the method of claim 1, wherein the strength of the nucleic acid and protein interaction is measured through fluorescence (page 207, col. 2, lines 13-17).

Regarding claim 8, Guschin et al teach the method of claim 1, wherein the nucleic acid sequence is selected from the group consisting of a nucleic acid having a predetermined sequence (page 205, col. 2, second full paragraph).

Regarding claim 9, Guschin et al teach the method of claim 1, wherein the protein is selected from the group of proteins consisting of a predetermined protein as indicated by the names of the proteins (page 210, col. 2, last paragraph).

Regarding claim 12 and 13, Guschin et al teach the method of claims 1 and 12, wherein the nucleic acid sequence is nucleic acid encoding a functional nucleic acid sequence such as a gene, e.g., β-globin gene (page 205, col. 2, first three lines of paragraph 3).

Therefore, Guschin et al meet the limitations of claims 1-5, 7-9, 12-13, of the instant invention.

Claim Rejections - 35 USC § 102(e)

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 4, 5, 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Taylor et al (US 6682893, Effective filing date January 1998). Regarding claims 1, 4, 5 and 14, Taylor et al. teach a method comprising immobilizing a nucleic acid (RNA, ss DNA or ds DNA) or a protein within a solid support wherein said solid support is a gel pad; contacting the nucleic acid and/or protein under conditions that allow the nucleic acid and/or the protein to interact and measuring the interaction of the nucleic acid and/or protein interaction via fluorescence (col. 7, lines 21-30 and col. 8, lines 28-42).

Therefore, Taylor et al meets all of the limitations of claims 1, 4, 5, 7 of the instant invention.

Claim Rejections - 35 USC § 102(a)

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 17, 19-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Arenkov et al (Analytical biochemistry, Vol. 278, pages 123-131, February 2000). Regarding claim 17, Arenkov et al teach a method of characterizing protein-protein interaction comprising: (a) immobilizing a protein within a solid support; (b) contacting the protein with a second protein under conditions which allow the proteins to interact;

(c) measuring the strength of the protein-protein interaction and repeating the steps (a) through (c) one or more times (up to ten times) (see Abstract and entire section "Materials and Methods").

Regarding claims 19, Arenkov et al. teach a method of claim 17, wherein the immobilized proteins used in steps (a) through (c) are different from the respective immobilized protein used in the first assay (see figure 4 and legend, page 128).

Regarding claim 20, Arenkov et al. teach the method of claim 17, wherein the solid support is gel pad (Abstract)

Regarding claim 21, Arenkov et al teach the method of claim 17, wherein the strength of the protein-protein interaction is measured through fluorescence (page 125, lines 1-4 of the last paragraph of column 1). Therefore, Arenkov et al meets the limitations of claims 17, 19-21 of the instant invention.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not

commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1-14, 17, 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (US 5,922,617, July 13, 1999) in view of Drobyshev et al (nucleic acids research, Vol. 27, pages 4100-4105, 1999) and further in view of Arenkov et al. (Analytical Biochemistry, Vol. 278, pages 123-131, February 2000). Regarding claims 1-3, 5-6, 8-11, 17, 19, Wang et al. teach a method for characterizing a nucleic acid-protein interaction or a protein-protein interaction, comprising: immobilizing a nucleic acid or a protein on a solid support, (b) contacting the nucleic acid and the protein or the protein and protein under conditions which allow the nucleic acid and the protein to interact; and measuring the strength of the nucleic acid-protein interaction or the protein-protein interaction. (col. 1, lines 66-67 and col. 2, lines 1-14, and col. 7, lines 52-54). The reference further discloses wherein a plurality of different components (nucleic acids or proteins) that are not predetermined sequences are immobilized at different addresses on the solid support and wherein the method steps are repeated to detect interaction between the components (nucleic acid or protein) col. 2, line 60 to col. 3, line 11 and col. 9, lines 24-25; see also col. 17, lines 56-67). Wang et al differ from the instant invention in that the reference does not teach wherein the nucleic acid or protein or immobilized within a gel pad(s).

Drobyshev et al. teach a method of detecting nucleic acid-ligand (dye) interaction comprising the steps of immobilizing a nucleic acid within a gel pad solid support, contacting the nucleic acid and the ligand under conditions which allow the nucleic acid

and ligand to interact; and measuring the strength of the nucleic acid-ligand interaction by measuring through Tm or a change in Tm (Abstract and page 4101, Section entitled "Materials and Methods). The reference teaches advantages of using gel pads as an immobilization support in oligonucleotide, DNA and protein arrays over the use of probes attached to a solid support. Drobyshev et al states that three-dimensional immobilization in gel pads provide higher capacity and a more homogeneous environment than heterophase immobilization on glass or filters (page 4100, col. 2 second full paragraph).

In a similar method to that of Drobyshev et al., Arenkov teaches a method of characterizing protein-protein interaction via the use of a gel pad(s) wherein one of said protein is immobilized within the gel pad microchip (abstract). Arenkov et al provides several advantages of using a microarray of gel-immobilized compounds on a chip such as a gel pad rather than conventional analytical devices, such as that taught by Wang et al.. Arenkov et al teach that one advantage of the use of a gel -pad microchip over conventional analytical devices is the possibility of massive parallel analysis. Arenkov et al teach that other advantages of using a gel support for fixation of biological compounds, such as e.g., proteins, is the large capacity for immobilized compounds. Arenkov et al state that the gel pads in an array are separated from each other by a hydrophobic surface, therefore, the gel pads can be used as a large number of individual microtest tubes to carry out specific interactions and chemical and enzymatic procedures (page 123, entire background section). Therefore, in view of the foregoing, one of ordinary skill in the art at the time of the claimed invention would have been motivated to have modified the method of Wang et al to encompassed the use of compounds

immobilized within a gel pad rather than on a solid surface to characterize nucleic acid or protein interaction. One of ordinary skill in the art at the time of the claimed invention would have been motivated to do so for the advantages taught by Drobyshev et al that gel pads as an immobilization support provides a higher capacity and a more homogeneous environment for analysis. Additionally, one of ordinary skill in the art would have been further motivated to have modified the method to encompassed the use of a gel pad as the solid support for the advantages taught by Arenkov that gel pads allow for massive parallel analysis.

Regarding claim 4, Wang et al. teach an embodiment of claim 1, wherein the nucleic acid is ss or ds DNA or RNA (col. 4, lines 10-53).

Regarding claims 12 and 13, Wang et al. teach an embodiment of claim 1, wherein the nucleic acid is a functional nucleic acid sequence, such as a promoter (col. 9, lines 35-40, see also col. 7, lines 41-59).

Regarding claim 14, Wang et al. teach an embodiment of claim 1, wherein the protein (transcription factor) is capable of modulating the activity of a gene or gene product (col. 7, lines 41-59 and col. 9, lines 35-40).

Regarding claims 7 and 21, Wang et al. teach an embodiment of claim 1, wherein the strength of the nucleic acid-protein interaction or the protein-protein interaction is measured through fluorescence (col. 7, lines 21-33). Therefore, Wang et al. meets all of the limitations of the instant invention of claims 1-4, 7-14, 17-19 and 21.

15. Claims 17, 19-21 are rejected under 35 U.S.C. 103(a) as obvious over Guschin et al. as previously applied above. Regarding claim 17, Guschin et al teach a method for

characterizing a protein-protein interaction comprising: (a) immobilizing a protein within a solid support; (b) contacting the protein with a second protein under conditions which allow the proteins to interact; (c) measuring the strength of the protein-protein interaction (page 207, col. 2, first full paragraph and lines 1-4 of the last paragraph and Figure 3). Guschin et al do not expressly teach repeating steps of the immunoanalysis steps of the protein. However, Guschin et al allude to this teaching. Specifically, Guschin et al teach in the abstract and background (page 203, last paragraph of col. 2 bridging col. 1, lines 1-8 of page 204) that the procedure reported herein comprises a gel photopolymeriziation technique to produce micromatrices of polyacrylamide gel pads. Guschin et al teach that a pin device for the manual application of compounds in solution onto the activated polyacrylamide gel for immobilization is described and states further that oligonucleotide, DNA and protein microchips have been produced by this method and tested and monitored with fluorescence microscope. At page 206, Guschin et al depicts the device for manual loading and immobilization. At page 207, Guschin et al disclose the reproducibility of the loading and immobilization of a fluorescently labeled oligonucleotide and depicts repetition of sample assay steps in Figure 3, and finally at pages 210 and 211, Guschin et al disclose three different proteins immobilized within a gel pad. Given the teaching that the same method and device are utilized for the oligonucleotides and proteins and additionally given the teaching of repetition of the sample assays for oligonucleotides and reproducibility of the loading and immobilization of oligonucleotides by the pin device, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention that the method and device of Guschin et al allows for repetition of sample step for protein as well as oligonucleotides.

Regarding claims 19, Guschin et al. teach a method of claim 17, wherein the immobilized proteins used in steps (a) through (c) are different from the respective immobilized protein used in the first assay (page 207, col. 2, first full paragraph and lines 1-4 of the last paragraph and Figure 6).

Regarding claim 20, Guschin et al. teach the method of claim 17, wherein the solid support is gel pad (page 205 and 207, section entitled "protein microchip").

Regarding claim 21, Guschin et al teach the method of claim 17, wherein the strength of the protein-protein interaction is measured through fluorescence (page 207, col. 2, second full paragraph and page 211, lines 1-8 and figure 6).

16. Claims 15, 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guschin et al as previously discussed above in view of Ahern et al. Regarding claims 15, 16, Guschin et al. teach a method for characterizing a nucleic acid-protein interaction or a protein-protein interaction, comprising: immobilizing a nucleic acid or a protein on a solid support, (b) contacting the nucleic acid and/or the protein under conditions which allow the nucleic acid and the protein to interact; and measuring the strength of the nucleic acid-protein interaction or the protein-protein interaction. Guschin et al. differ from the instant invention in that the reference does not teach the method is in the form of a kit. However, Guschin et al. teach reagents that would be necessary in the kit such as solid support, buffers and dyes. In a scientific article, Ahern teaches the advantages of using a kit. Ahern teaches that a kit provides convenience, time management and ease of practicing to the investigator (page 4, second-forth paragraphs). Therefore, in view of the teachings of Ahern, one of ordinary skill in the art would have been motivated at the time

of the claimed invention to have modified the nucleic acid and/or protein interaction as taught by Guschin et al to encompass a kit. One of ordinary skill in the art would have been motivated to do so for the advantages taught by Ahern that a kit provides convenience, time management and ease of practicing to the investigator.

17. Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arenkov et al as previously discussed above in view of Ahern et al. Regarding claims 22 and 23, Arenkov et al. teach a method for characterizing a protein-protein interaction comprising: immobilizing a protein on a solid support, (b) contacting the protein under conditions which allow the protein to interact with the protein immobilized on the support; and measuring the strength of the nucleic acid-protein interaction or the protein-protein interaction. Arenkov et al. differ from the instant invention in that the reference does not teach the method is in the form of a kit. However, Arenkov et al. teach reagents that would be necessary in the kit such as solid support, buffers and dyes. In a scientific article, Ahern teaches the advantages of using a kit. Ahern teaches that a kit provides convenience, time management and case of practicing to the investigator (page 4, second-forth paragraphs). Therefore, in view of the teachings of Ahern, one of ordinary skill in the art would have been motivated at the time of the claimed invention to have modified the protein-protein interaction as taught by Arenkov et al to encompass a kit. One of ordinary skill in the art would have been motivated to do so for the advantages taught by Ahern that a kit provides convenience, time management and ease of practicing to the investigator.

Conclusion

18. No claims are allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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CYNTHIA WILDER
PATENT EXAMINER
6/30/2004